Aclaris Therapeutics Announces Positive Update on Phase 2 Results after a 3-month Follow-Up of A-101 45% Topical Solution for Potential Treatment of Common Warts

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- Primary, secondary, and exploratory endpoints of Phase 2 trial met during 8-week treatment period
- After treatment completed, greater improvement vs. placebo observed in 3-month post-treatment follow-up evaluation
- If approved, A-101 45% would be the first FDA-approved treatment for common warts

WAYNE, Pa., March 19, 2018 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS) today announced positive results from the 3-month, post-treatment, follow-up evaluation period of its twice-weekly placebo-controlled trial (WART-203) of A-101 45% topical solution (A-101 45%), an investigational new drug consisting of a proprietary high-concentration hydrogen peroxide topical solution being developed as a prescription treatment for common warts (verruca vulgaris). As previously reported, A-101 45% met the trial endpoints related to reduction and clearance of common warts versus placebo during the initial 56-day treatment period. Over the 3-month post-treatment follow-up period, greater improvements in common wart reduction and clearance vs. placebo were observed among subjects treated with A-101 45%.

WART-203 evaluated the safety and efficacy of A-101 45% as compared to placebo (vehicle) in a randomized, double-blind, vehicle-controlled trial with a 3-month post-treatment follow-up period. This 3-month follow-up period was designed to understand the clinical effect of the twice weekly treatment regimen for 8 weeks and durability of the clinical effect.

Statistically significant results related to common wart reduction and clearance were previously reported after the 56-day treatment period. Subjects then continued into the 3-month follow-up portion of the trial. The WART-203 trial evaluated 159 subjects who self-administered either A-101 45% or placebo twice weekly through Day 56, for a total of 16 treatments. Of the 159 subjects randomized, 151 subjects completed the 3-month post-treatment follow-up period in compliance with the protocol. Each subject had between one and six warts at baseline. The primary efficacy analysis was assessed based on the mean change from baseline in the Physician's Wart Assessment (PWA) scale score at Day 56 (Visit 8) and Day 134 (Visit 13). The PWA score is a four-point scale of the investigators' static assessment of the severity of a target wart at a particular time point. At the end of the 3-month follow-up period, at Day 134, subjects in the A-101 45% group showed greater improvement vs. placebo.

The primary efficacy analysis of the WART-203 trial:

- At Day 56, the mean reduction in PWA score on the target warts was 0.87 points in subjects who received A-101 45%, compared to a mean reduction of 0.17 points for the subjects treated with placebo ($p<0.001$). At Day 134, the mean reduction in PWA score on the target warts was 1.0 points in subjects who received A-101 45%, compared to a reduction of 0.39 points for subjects that received placebo, a result that was statistically significant ($p = 0.0004$).

Secondary and exploratory endpoints of the WART-203 trial:

- At Day 56, the percentage of all treated warts that were clear (PWA= 0) was 30.2% in subjects who received A-101 45%, compared to 9.2% among subjects in the placebo group ($p<0.0001$). At Day 134, the percentage of all treated warts that were clear was 39.2% in subjects who received A-101 45%, compared to 17.2% among subjects in the placebo group ($p<0.0001$).
- At Day 56, the proportion of subjects achieving target wart clearance (PWA= 0) was 25.3% among those who received A-101 45%, compared to 2.6% among subjects in the placebo group ($p<0.0001$). At Day 134, the proportion of subjects achieving target wart clearance was 37.3% among those who received A-101 45%, compared to 11.8% among subjects in the placebo group ($p<0.0002$).
- At Day 56, the proportion of subjects with all treated wart(s) clear (PWA= 0), stratified by the baseline number of warts treated (1-6), was 19.0% among those who received A-101 45%, compared to 2.6% among subjects in the placebo group ($P=0.001$). At Day 134, the proportion of subjects with all treated wart(s) clear, stratified by the baseline number of warts treated (1-6), was 33.3% among those who received A-101 45%, compared to 7.9% among subjects in the placebo group ($P=0.0002$).

Safety Results

- There were no treatment-related serious adverse events among subjects treated with A-101 45%.
- A-101 45% was generally well tolerated through visit 13 (Day 134).

"We are extremely pleased by these results," said Stu Shanler, M.D., Chief Scientific Officer. "This is an important milestone for the A-101 45% wart program, and these data further substantiate the potential clinical utility of our proprietary formulation of A-101 45% topical solution. Based on these results, we plan to meet with the FDA mid-year regarding our Phase 3 program for the treatment of common warts. We expect to initiate our Phase 3

program in the second half of 2018."

About Common Warts
Common warts, also called verruca vulgaris, affect more than 22 million Americans. Prevalence is higher in children than adults. Common warts most often appear on the hands and usually look like skin-colored papules with a rough surface. They result when skin cells are infected by human papillomavirus (HPV) and spread via direct contact or contact with infected surfaces. Though common warts may resolve without treatment, they can persist for years. Over-the-counter topical treatments are first-line therapy for common warts but are marginally effective and slow to work. More than two million patients seek treatment for common warts from healthcare professionals each year, possibly because of social stigma, embarrassment or symptoms such as pain, bleeding, itching and burning. There are currently no FDA-approved prescription medications for warts, and existing treatment procedures are often painful or invasive, can have undesirable outcomes like scarring or dyspigmentation, and often require repeat visits.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company committed to identifying, developing, and commercializing innovative therapies to address significant unmet needs in dermatology, both aesthetic and medical, and immunology. Aclaris' focus on market segments with no FDA-approved medications or where treatment gaps exist has resulted in the first FDA-approved treatment for raised seborrheic keratoses and several clinical programs to develop medications for the potential treatment of common warts, alopecia areata, and vitiligo. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "believe", "expect", "may", "plan," "potential," "will," and similar expressions, and are based on Aclaris' current beliefs and expectations. These forward-looking statements include expectations regarding Aclaris' clinical development of A-101 45% for the treatment of common warts, including the expected timing for commencing a Phase 3 clinical trial. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Aclaris' reliance on third parties over which it may not always have full control, risks associated with maintaining its intellectual property portfolio and other risks and uncertainties that are described in Aclaris' Annual Report on Form 10-K for the year ended December 31, 2017, and other filings Aclaris makes with the SEC from time to time. These documents are available under the "Financial Information" section of the Investors page of Aclaris' website at http://www.aclaristx.com. Any forward-looking statements speak only as of the date of this press release and are based on information available to Aclaris as of the date of this release, and Aclaris assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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